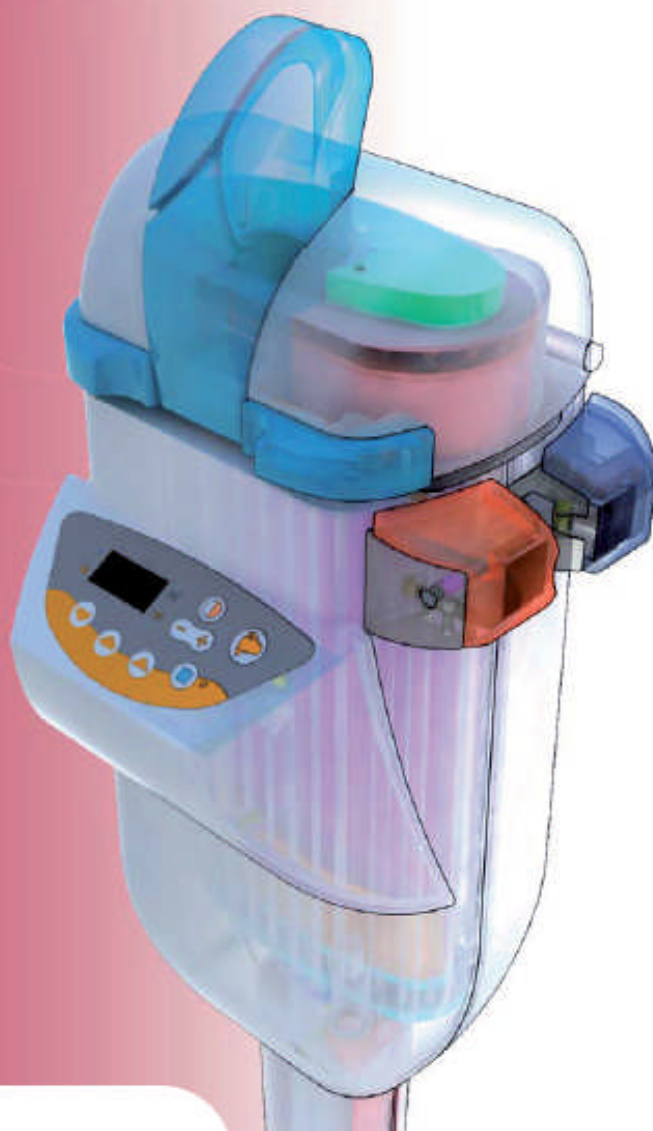


SBi

User Manual

SBI 5000-CT
5002-CT

Automatic injection system
for contrast agents
in soft bags



Medex | by Guerbet
Link in imaging





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4. GLOSSARY



IMPORTANT WARNINGS: WARNINGS AND PRECAUTIONS FOR USE

Before using the SBI injection system, carefully read the paragraphs below and make sure that you understand them completely. If you neglect to do so, you run the risk of causing material damages or injuries. If you have questions, get in touch with Medex or Guerbet customer service + the supplier.

Warnings

The dangers mentioned here entail a risk of serious injuries to the patient or operator. Read this section carefully.

- ✚ The SBI injection system is only used to inject contrast agent solutions intravenously into human patients before CT examinations, followed by an injection of normal saline in the case of version SBI 5002-CT. It is not for any other use. Only use it for the specified application.
- ✚ The contrast agent must be placed in the contrast agent bag and the saline in the saline bag. Reversing the contents of the bags can be dangerous for the patient and lead to a false diagnosis.
- ✚ The two-liquid function is for injections from the single-dose container. Do not use the two-liquid function for injections from the multi-dose container or in more than one patient.
- ✚ This device is not intended for administration of medicinal products or chemotherapy. It must not be used for applications other than that for which it is intended.
- ✚ The SBI injection system must be used correctly to avoid air embolisms. Once the bag is filled with the desired volume, **YOU MUST REMOVE ALL THE AIR IN THE BAG AND LINES WITH THE INJECTOR. IF THIS PRECAUTION IS NOT TAKEN, SERIOUS OR MORTAL INJURIES CAN RESULT.**
- ✚ In the event of malfunction, shut the device off immediately and disconnect it rapidly from the patient. Check that everything is functioning properly again before reconnecting. Turn the system power on, activate it and proceed with a test injection. If the problem is resolved, reconnect the patient. If the failure message is still displayed and cannot be corrected, or if the injector still does not function properly, **STOP USING** the SBI injection system until the problem has been correctly diagnosed and resolved.
Get in touch with your local Guerbet distributor or another certified Medex distributor (contact information on the last page).
- ✚ Carefully select the flow rate on the workstation to avoid inadvertently causing an injection rate that is too high. **AN INJECTION RATE THAT IS TOO HIGH CAN INJURE THE PATIENT.** Check all the programme parameters and injection settings before activating the injector.
- ✚ The SBI injection system is not compatible with magnetic resonance imagers (MRI) and must not be used in MRI.
- ✚ There is a risk of explosion when the SBI injection system is in the presence of inflammable anaesthetics. Never use the device in the presence of inflammable gases. This device must not be used in the presence of **INFLAMMABLE ANAESTHETICS MIXED WITH AIR, OXYGEN OR NITROUS OXIDE.**
- ✚ The efficacy of the SBI injection system has been demonstrated when used with Medex accessories. To avoid incompatibility or a possible malfunction, only use Medex consumables dedicated to the SBI.

-
- ✚ Once the bag is filled with contrast agent, it must be used in the next few hours. Bacterial proliferation is possible if the contrast agent is exposed to air. Always comply with the manufacturer's instructions on the label for handling, filling, use, storage and disposal.
 - ✚ To avoid transmission of any infections, comply with aseptic conditions when you handle the contrast agent, the saline or any other device or means of transport or administration of the contrast agent or saline, particularly bags, extension lines and patient connections. Consumables dedicated to the SBI injection system have been specifically designed for use with one or more patients. During multipatient use, the consumables must be protected downstream by changing the SECUFILL line for each patient (line with a patented double check valve). **BAGS MUST BE FILLED ONLY ONCE**. At the end of use, discard them in compliance with rules relating to biologically hazardous materials.
 - ✚ To guarantee aseptic conditions while avoiding accidental spills or damage to the apparatus, always check that the packaging of the line and bag, as well as the bag itself, are intact. If it has been opened or shows visible damage, do not use the set.
 - ✚ Accidental liquid spills can cause electrocution. Avoid spilling the contrast agent, saline or any other liquid onto the injections system. It must never be soaked in a liquid, even during cleaning. This would create conduction between the metal parts of the system and the patient.
 - ✚ Only use the SBI system when it is connected to an adequate electrical source. Connect the device and its monitor directly to an electrical outlet that is grounded according to hospital standards. Never use an extension cord. Do not try to connect the system to a two-wire outlet without a ground wire, even with an adapter. Immediately replace any worn or frayed cables.
 - ✚ The SBI injection system and any electrical apparatus connected to the patient or catheter must be electrically insulated or adequately grounded to avoid electrocution.
 - ✚ Opening a component of the SBI injection system also entails a risk of electrocution. Do not try to repair or modify the system or any of its components. These devices contain no parts that can be replaced by the user. Internal components must only be serviced by a certified Medex or Guerbet technician.
 - ✚ Always ask the patient to inform the technicians immediately in the event of pain or a new sensation during the injection or examination so that risks of extravasation, for instance, can be detected.

Precautions for use

- ✚ Use of a contrast agent injector in children under two years of age must be the subject of initial risk analysis by the radiologist.
- ✚ If the injector is used in children under two years of age, adapt the injection rate to the chosen administration route (intracranial, foot, hand) to take into account any vascular fragility (the minimum flow rate of the SBI injection system is 0.5 ml/s).

1.Presentation

1.1 Introduction

Contrast agent injection must be a process that is reliable and easy for both the radiologist and the patient. The various automatic operations must not jeopardise safety. A perfect repetition of actions allows a comparative study based on different parameters, whether planned or actually performed.

The main criteria on which the design of this injector is based are precision, comfort and safety. Its innovative principle consists in producing a uniform hydraulic pressure on a soft bag filled with contrast agent (up to 2100 kPa / 300 psi). The technical characteristics of the injection are the same as for conventional syringe injectors.

However, among the advantages of the new concept that we discuss in this manual are the following improvements:

- ✚ **Hygiene** during handling.
- ✚ **Patient comfort** thanks to a smooth injection (reduced side effects due to the high flow rate of a bolus, as the patient does not feel the high-pressure thrust of conventional syringe injectors).
- ✚ **Injection from a multi-dose container** (bag containing up to 500 ml), and to more than one patient, is possible in the single-liquid mode if aseptic conditions are maintained and Medex SECUFILL patient lines with check valves are used (see the instruction leaflet). Do not use the two-liquid function for injections from the multi-dose container or in more than one patient.
- ✚ **Shorter preparation time** with a rapid filling system outside the examination room and with increased hygiene.
- ✚ **Safety**: impossible to proceed with the injection without first purging the system (avoiding the risk of accidental air injection). In addition, a sensor under the injector head ensures perfect control of the injection.
- ✚ **Cost reduction** for medical devices.

1.2 Description of the injector, installation and environment

The three main components are:

- ✚ **The injector head** in which the soft bags are placed.
- ✚ **The power unit** that produces pressure.
- ✚ **The monitor**.



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1.2.1 Injector head

The injector head of model SBI 5000-CT uses **single-bag** kits and the injector head of model SBI 5002-CT uses both **single- and double-bag** kits.

The main difference of SBI 5002-CT is its possibility to combine contrast agent and normal saline injections according to sequences chosen by the user to correspond to the development of new injection protocols.

The injector head is equipped with a **hydraulic pressure sensor** that guarantees better safety and higher precision than with syringe systems.



- 1 OPEN** button: opens the depressurised actuator bag to remove the bag(s) of solution (for injection) from the injector.
- 2 RAPID PURGE**: rapid purge of air in the bag(s).
- 3 SLOW PURGE**: slow purge of air from the bag(s).
- 4 VALIDATION** button: validation of an action.
- 5 INJECTION** button: starts injection from the injector head.

- 6 CONTRAST** button: only used on SBI 5002-CT for the double-bag mode. It controls the movement of the tube clamp for inserting and removing bags. It is used to select one of the two bags for purging.
- 7 MINUS** button: not used.
- 8 PLUS** button: not used.
- 9 Blue** light indicates an ongoing operation on the saline solution.
- 10 LCD** screen: indicates system status and procedure to follow (with a static or scrolling text).
- 11 Orange** light: indicates an ongoing operation on the contrast agent.
- 12 Orange** light: indicates that the head is ready for injection.



1.2.2 Power unit

The power unit produces uniform hydraulic pressure on the bag(s) of solution for injection (contrast agent/normal saline). The flow rate of 0.5 ml/s to 8 ml/s is precisely adapted to ensure its regularity according to the pressure, which can vary depending on the patient, the catheter size, the viscosity of the contrast agent injected and the patient lines, etc..



1 Removable cover

2 Ventilation grid

3 On/off switch

4 Monitor connection

5 Injector head connection

6 On/Off light

7 Hydraulic connection with the tube clamp

8 Hydraulic connection with the actuator bag

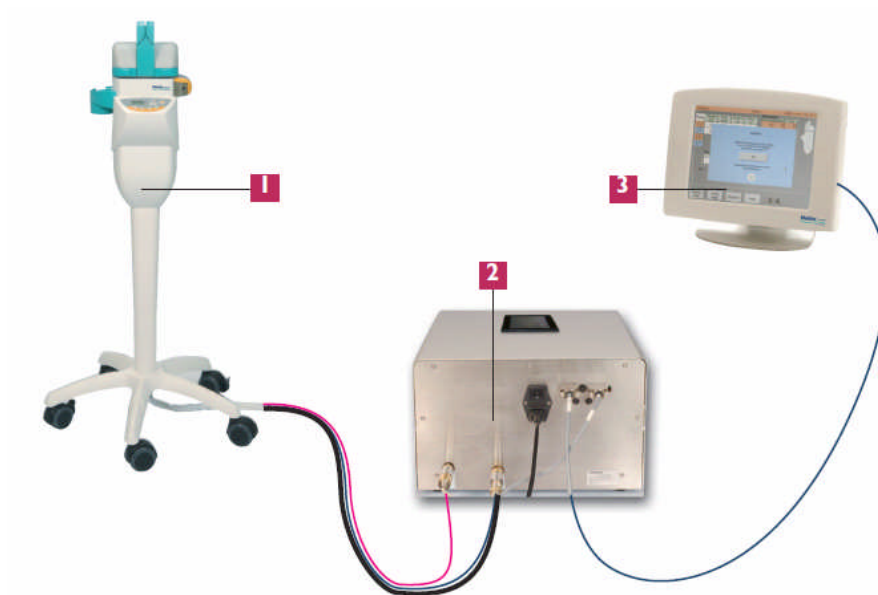
1.2.3 Monitor

A 10.4" **colour touchscreen** monitor with a resolution of 800 x 600 guides the user in **real time** for the injection parameters as well as for safety, saving examinations, system status, maintenance and software updating with a USB key.



1.2.4 Installation

The three components (injection head, power unit, monitor) are connected as follows:



1 Injector head

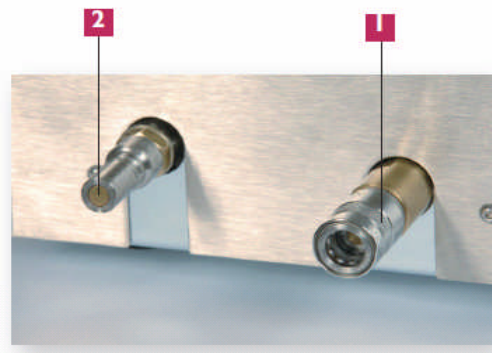
3 Monitor

2 Power unit

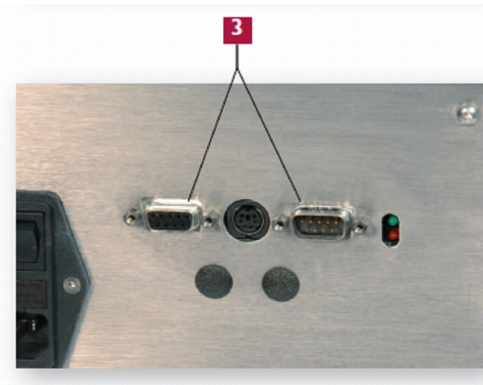
The connections to the power unit differ to avoid any error.



Power unit

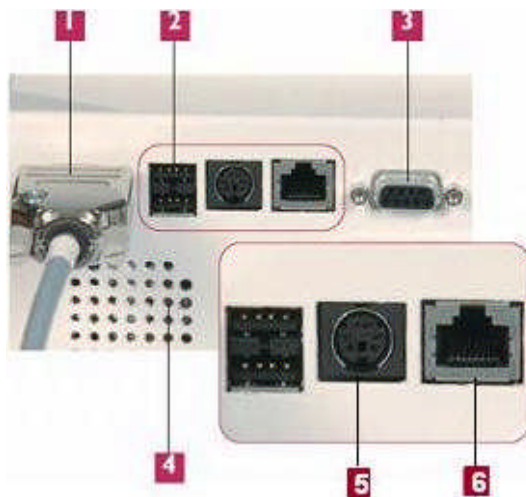


- 1** Female hydraulic connector: rapidly locked by pressing on the sides, unlocked by pushing the ring toward the box. After unlocking, the two ends of the connector are automatically sealed (flush-face self-sealing connector technology).
- 2** Only for the SBI 5002-CT. Male hydraulic connector (smaller) for the tube clamp: locked rapidly by pressing on the sides, unlocked by pulling the ring towards you. After unlocking, the two ends of the tube are automatically sealed.
- 3** Two D-sub 9 connectors: after inserting the connectors, lock them with the two side screws (2 screws per connector).



Monitor

The other connections behind the monitor are only used for servicing and other possible accessories (except for the D-sub 9 with the power unit).



- 1** D-sub 9 connector to the power unit
- 2** Two USB ports for updating and accessories
- 3** Manual controller connection
- 4** Loudspeaker
- 5** Connection for mouse or keyboard
- 6** Ethernet connection for maintenance

PRECAUTIONS FOR INSTALLING THE POWER UNIT:

To ensure optimal device function, the power unit has an air extraction grid on the top. The location chosen for installing the power unit must comply with the following restrictions:

- ✚ Do not close it in a cupboard, cabinet or a confined space.
- ✚ Give preference to areas with no risk of spraying; do not place a mug or cup of coffee on the cover.
- ✚ Do not cover the ventilation grid (cartons, sheets, rags, etc.).
- ✚ Do not block the air inlets at the rear of the power unit
- ✚ The hydraulic hose must not be bent by a radius of less than 50 mm at the risk of irretrievably deteriorating the device.

Connecting and/or disconnecting cables and/or hydraulic connectors when the injector is operating can have serious consequences. Starting the injector without connecting all the components can also cause operating problems.

Medex refuses all responsibility in the event of an incident.

1.3 Guarantee and maintenance contract

The guarantee is valid for one year and covers maintenance and parts.

The following are not covered by the guarantee:

- ✚ Any damage caused by using the injector in a manner not recommended by Medex,
- ✚ Deterioration caused by shocks, liquids and prolonged exposure to sources of heat,
- ✚ Deterioration of the actuator bag by sharp instruments (tools, scissors, rings, etc.),
- ✚ Servicing by unauthorised personnel,
- ✚ Software errors or deterioration due to uncontrolled an external disturbance.

At the end of the guarantee, a maintenance contract is required, whose terms are available upon request.

2. Using the injection system

2.1 Particularities

CHARACTERISTICS	SBI 5000-CT	SBI 5002-CT
■ Performance		
Bag capacity	500 ml	250 ml contrast agent + 250 ml saline
Total programmable volume	200 ml	
Flow rate	0.5 to 8 ml/s	
Maximum pressure	2100 kPa = 300 psi ± 40 kPa = 5.7 psi	
Number of phases	4	4 with choice of type of liquid
Interval between 2 phases	0 to x seconds (see page 34)	
Rapid purge	20 ml/s	
Slow purge	5 ml/s	
X-ray delay	0 to 999 s	
Index of protection	IP20	
Software	Single-bag	Single-bag and double-bag
■ Installation and startup		
Voltage	230 V AC, 50-60 Hz	
Current	3 A	
Power consumption	240 VA	
Fuse / plug	T 3.15A - 230V 5 x 20	
Operating temperature	15°C / 30°C	
Installation	On mobile base or suspended	

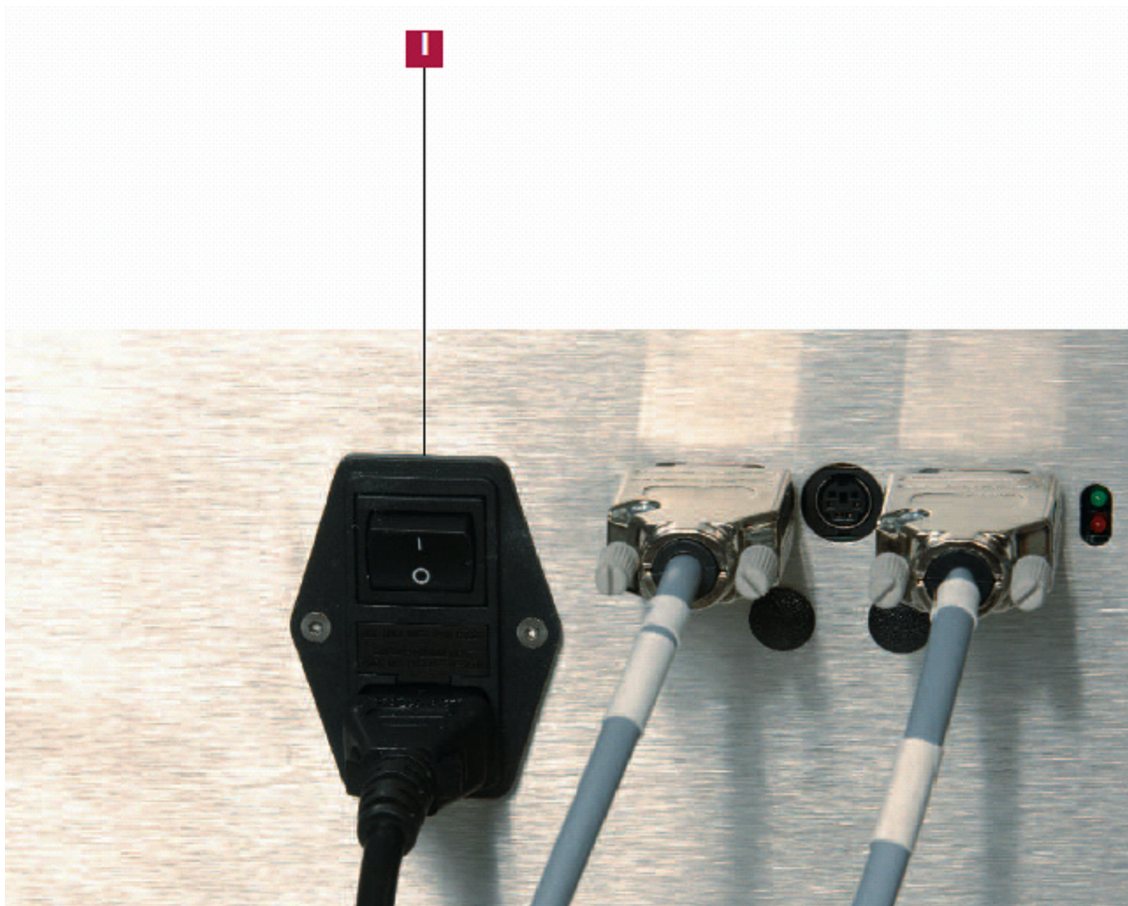


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2.2 Starting the injection system

2.2.1 Power-on and startup

To turn on the power, press the **On/Off** switch on the back of the power unit.



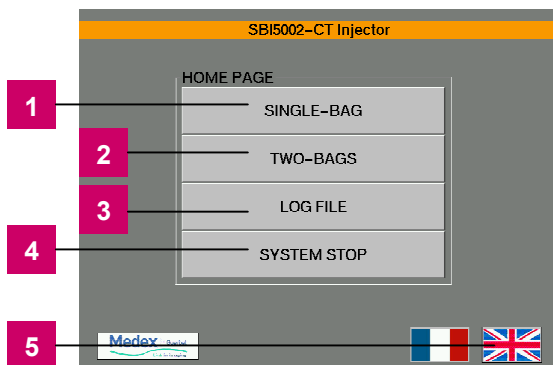
1 On/Off switch



After turning the power on, the screen temporarily displays **Welcome**.

2.2.2 Selecting the usage mode

The home page is displayed.



- 1 Single-bag button**
→ access to injection mode for contrast agent alone
- 2 Double-bag button**
→ access to injection mode for contrast agent and normal saline (only active for SBI 5002-CT).
- 3 Log button**
→ System failure and error log
- 4 Stop button**
→ to stop the application
- 5 Language button**
→ press the flag corresponding to your language

■ For SBI 5000-CT, select the single-bag mode.

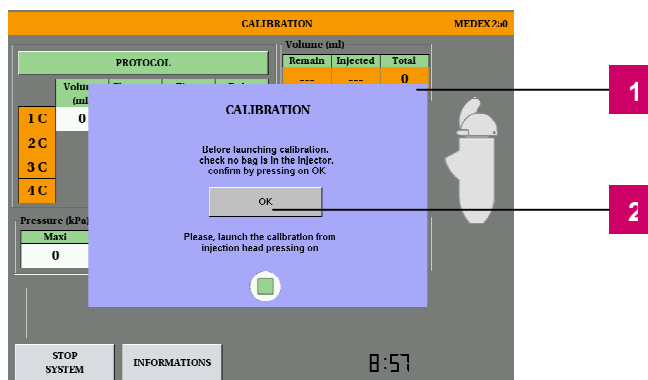
■ For SBI 5002-CT, select the single-bag or double-bag mode.

You can return to the main menu later on.

2.2.3 Calibration

This operation takes place every time the injector is started.

Before this calibration phase (= homing), a dialogue box appears and indicates the procedure to follow.




1 Warning message before calibration

2 Button to confirm that there is no bag in the injector head

- Read the instructions in the dialogue box and make sure that there are no bags in the injector

If one or two bags are present in the injector head, they must be removed before the calibration phase:

- Open the lid

- Press once  (**OPEN**).

The injector opens the actuator bag. When the bag(s) is/are removed, the movement for opening the actuator bag can be stopped by pressing any key on the keyboard. The message 'Close the lid' appears.

- Close the lid and press the validation button

- Confirm with **OK**. The word 'OK' turns grey on the monitor and the message 'remove bags and validate to start calibration' is displayed on the control panel

Warning: The lid of the injector head must remain closed during the whole calibration procedure.

- Confirm on the injector head  (**VALIDATE**)

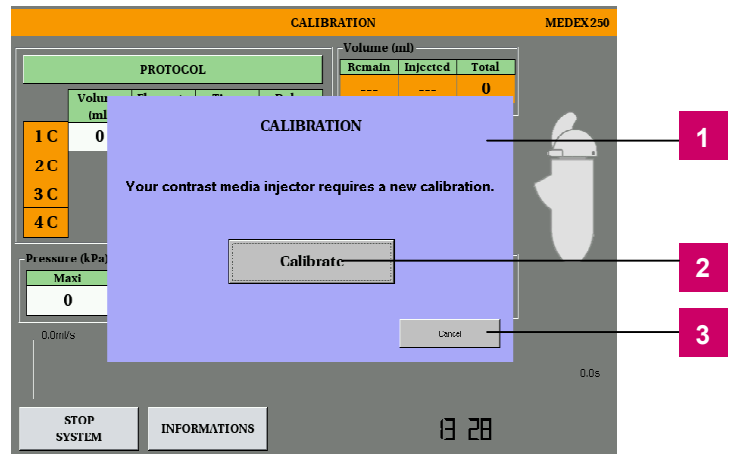


- The message 'Please wait' appears on the control panel of injector head.
- The message '**calibration OK**' appears, followed by a sound signal indicating that calibration is proceeding correctly.
- The message '**opening**' appears. Three rapid beeps also indicate to the user that calibration is complete.
- The message '**insert the contrast agent and validate**' appears, which means that calibration is over.



Depending on the configuration of the injector, a new calibration may be required after 3 hours. The following message will be displayed on the console:

Calibration occurs only outside the phases of preparation and injection. It improves the measure of the bags volumes and is recommended to accept it. However, cancellation is possible.



- 1 Warning message before calibration
- 2 Button to confirm calibration

- 3 Button to cancel calibration

Before performing the new calibration, read the instructions on the console and ensure that no bag is left in the injector and no patient is connected to the injector :

To continue the procedure, refer to the chapter 2.2.3 – Homing.



2.3 Preparing bags

2.3.1 Filling empty bags

For the contrast agent, the operator has the choice of directly using the prefilled ScanBag® developed by Guerbet or filling the empty bag supplied by Medex (bag with yellow writing). For normal saline, only the empty bag supplied by Medex is suitable for the SBI injection system (bag with blue writing).

The soft bags developed by Medex are easily and safely filled from a bottle with the rapid filling system, Fill Fast, which improves hygienic conditions.

The injector can use bags containing up to 500 ml of contrast agent in the single-bag mode. Depending on the model, there are one or two bags, an infusion set and a patient line: 150 cm (straight) or 200 cm (Y form) with check valve.

With the Fill Fast system, the filling can be done outside the examination room and at the same time (preparation), which reduces the handling time. This operation involves creating a slight positive pressure in the bottle to accelerate the transfer from bottle to bag. The Fill Fast system is supplied as standard equipment with the injector.

Warning about the consequences of using inadequate bags:

Only bags listed in the Medex **Catalogue medical devices** can be used.

Using inadequate bags can have serious consequences, such as:

- Non compliance with programmed volumes and flow rates.
- Deterioration of the actuator bag in the injector head.
- An inappropriate bag design can result in insufficient air removal and potentially an accidental injection of air with the risk of air embolisms.

Medex refuses all responsibility in the event of an incident.

Always connect the Luer lock with the green ring to the contrast agent bag. Connect the Luer lock on the blue tube to the bag of saline (only for the double-bag mode).

**Fill the bag with a volume of contrast agent corresponding to the volume to be injected (taking into account the volume discarded during the purge).
Never refill a bag after it has been used.**



Bag filling is explained in detail in the user instructions, such as below:



After removing the bag from its packaging, insert it into the slot. Fit the stainless steel Fill Fast ring into the spike hole, pressing firmly (**Fig. 1**).

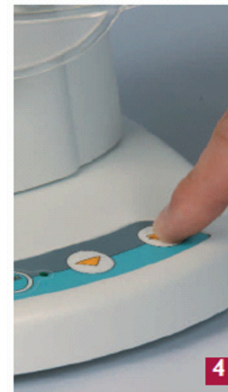
Then remove the spike cap (**Fig. 2**).



Immediately press the bottle onto the spike (top towards the bottom and to the right) (**Fig. 3**).

Press the button constantly to fill the bag (**Fig. 4**). If more than one bottle is required, remove the empty bottle and insert a full bottle.

Note: With this filling system, two bags can be filled consecutively (normal saline and contrast agent). When prepared in advance, the bottle can remain on the spike until it is used for the next patient, guaranteeing the sterility of the contrast agent (closed system).



When the bag or bags have been filled from one or more bottles, remove everything (**Fig. 5**).

Separate the bag from the spike keeping the bag straight (**Fig. 6**).



Connect the bag to the extension line supplied with the bag. If necessary, wedge the bag behind the Fill Fast (**Fig. 7**).

Proceed in the same manner to fill the two bags (contrast agent, normal saline) in the double-bag mode. It takes approximately 8 seconds at high speed to fill 100 ml of contrast agent.

Note: The extension lines supplied with the Medex bag kits are all equipped with check valves that prevent the reentry of air into the bags after they are purged. Medex recommends purging the residual air in the bags before connecting the extension line.

This operation has the following advantages:

- It facilitates the insertion of the bags into the injector head by reducing their size.
- It optimises the purge time.
- It further reduces the risk of accidental air injection.

When the bags are filled and connected to the patient line by a male Luer Lock, they can be inserted into the injector head. A **scrolling** message says to insert **the contrast agent bag**, whatever the usage mode selected in the main menu.

2.3.2 Preparing the ScanBag®

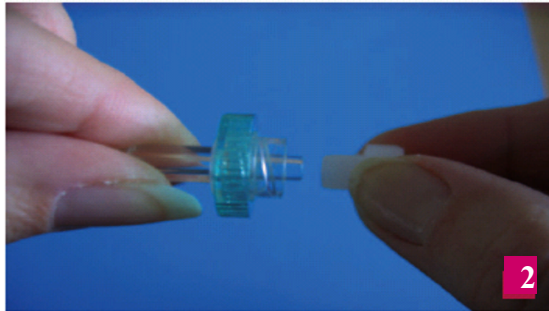
The advantage of using the prefilled contrast agent bag (ScanBag®) with the SBI injector is that **no product transfer is required, which enhances the aseptic conditions and saves time.**

The system remains closed, which limits any risk of contamination. Choose the bag volume according to the volume to be injected (taking into account the volume discarded during the purge).

Comply with the following connection instructions:



- 1 Remove the ScanBag® from its packaging.



- 2** Remove the white cap at the end of the extension line with the green ring (foolproof device)



- 3** Remove the red (350 concentration) or blue cap (300 concentration) from the ScanBag®



- 4** Connect the extension line to the ScanBag®



- 5** Break the removable part of the safety system on the ScanBag® (as described on the packaging of the ScanBag®)



- 6** The ScanBag® is ready for insertion into the SBI injector head (actuator bag)

2.3.3 Selecting the bag kit

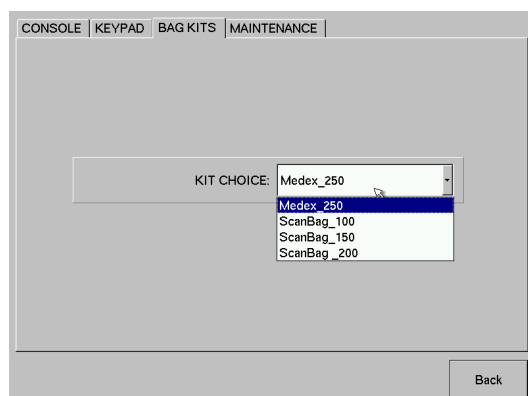
The bag kit must be selected.

This kit refers to the size of the bags used. This information informs the injector of the container volume that must be deducted from its measurement.

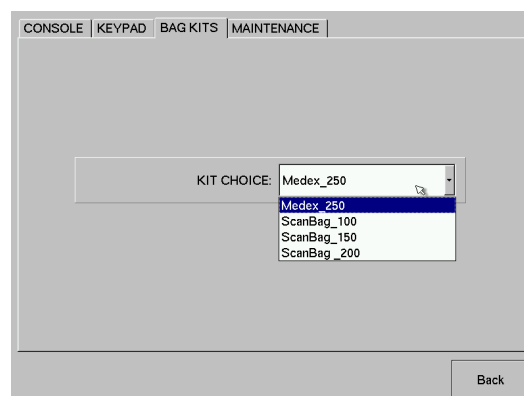
To open the bag kit window:

1 - Press the **Information** button in the main window

2 - Select the tab **Bag kits**



double-bag version

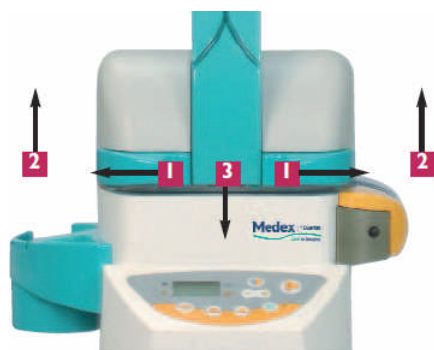


single-bag version

An oversight or error in the choice of the kit can result in false information on the volume(s) actually present

2.3.4 Inserting the bag in the single-bag mode

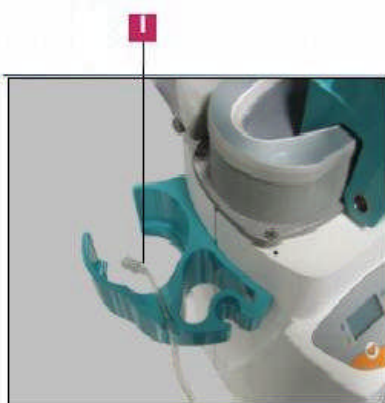
Open the lid:



- 1** Push the buttons outward
- 2** Tilt the lid backwards
- 3** Tilt the spout forwards



Inserting a single-bag kit:



1 Press the end of the tube into the cupholder*

2 Insert the contrast agent bag into the injector

3 Put the green ring (foolproof device) into the slot, adjust and wedge the tube into the groove in the spout

4 Close the spout

5 (Not represented) Close the lid without forcing it. The buttons should lock automatically

6 Press the validation button



7 This message appears: 'Measuring contrast agent volume... Please wait...'

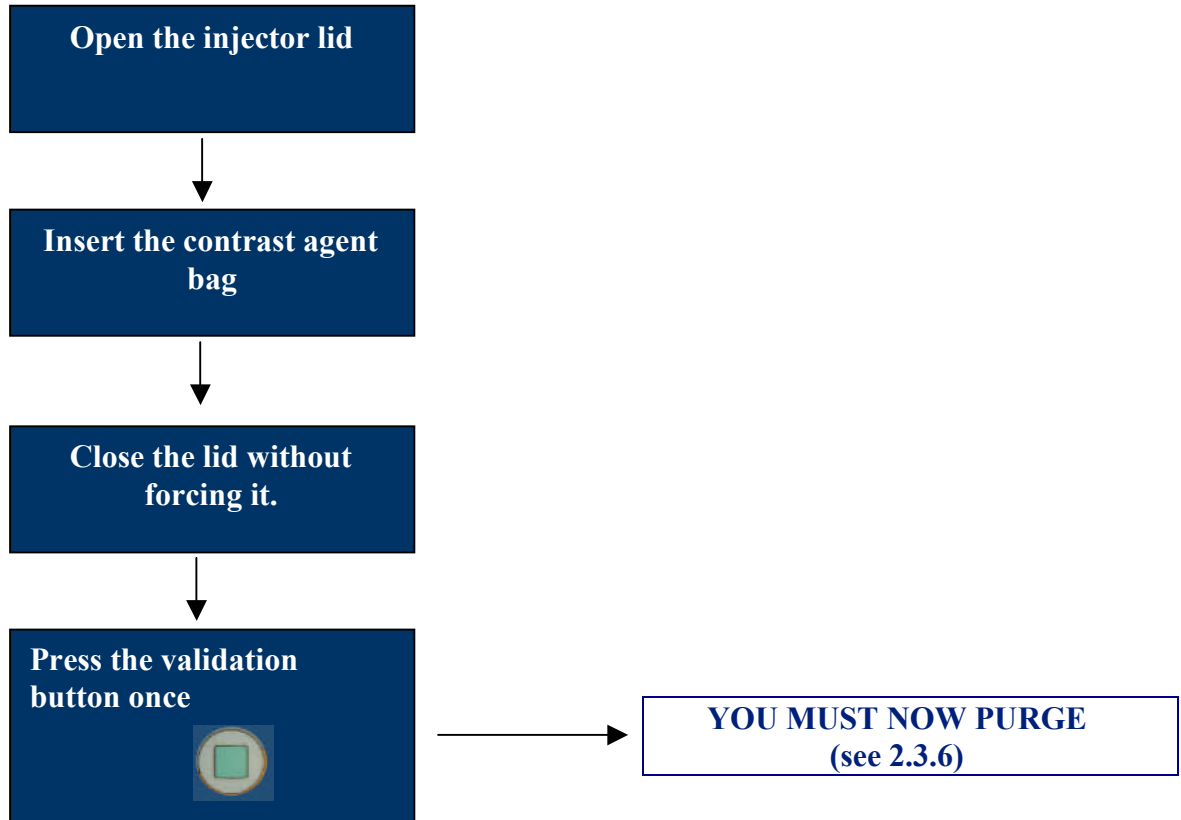
8 'Purge' blinks

* Type of cup used: standard plastic cup or any cup as long as it only rests on the upper ring.

Maximum filling recommended: $\frac{3}{4}$ of the cup (to reduce the risk of contrast agent escaping if the cup is knocked)

Push the tube into the cupholder groove: make sure that end of the tube does not extend too far into the cup. This is to avoid contact between the tube and contrast agent when the cup is full.

SUMMARY





2.3.5 Inserting bags in the double-bag mode

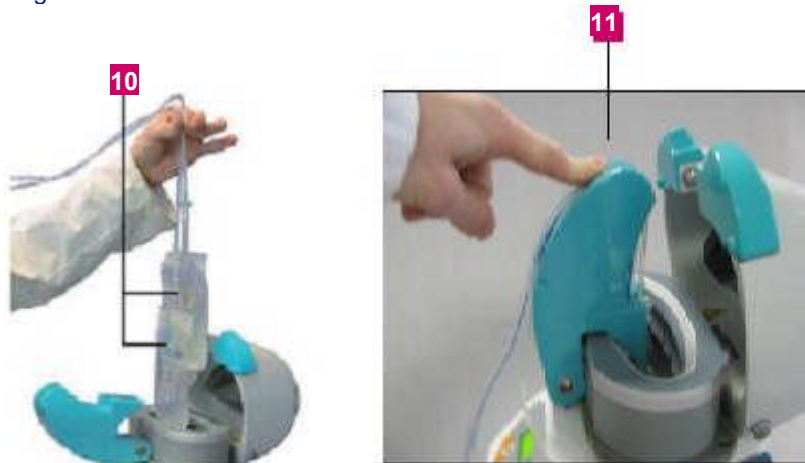
Inserting a double-bag kit

Repeat steps 1 to 7 in the single-bag procedure:

(Note: during the measurement of contrast agent bag volume, the bag of saline can be placed on its support next to the cupholder.)

8 'Contrast agent measurement terminated. Insert the two bags and validate' is displayed after beeps

9 Remove the bag



10 Insert the contrast agent and saline bags into the actuator bag. **Place the saline bag in front and slightly below the contrast agent bag**

11 Close the spout

12 Put the green ring (foolproof device) into the slot, adjust and wedge the tube into the groove in the spout

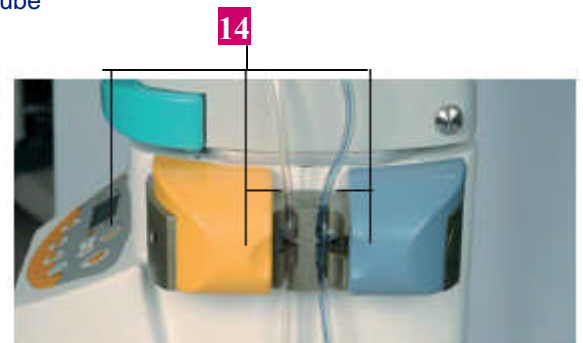
13 Close the lid

14 Place the transparent tube into the tube clamp next to the contrast agent (orange ring) and place the blue tube into the tube clamp next to the saline (blue ring). To move the tube clamp, press the button

15 Finally, press the button (validation)

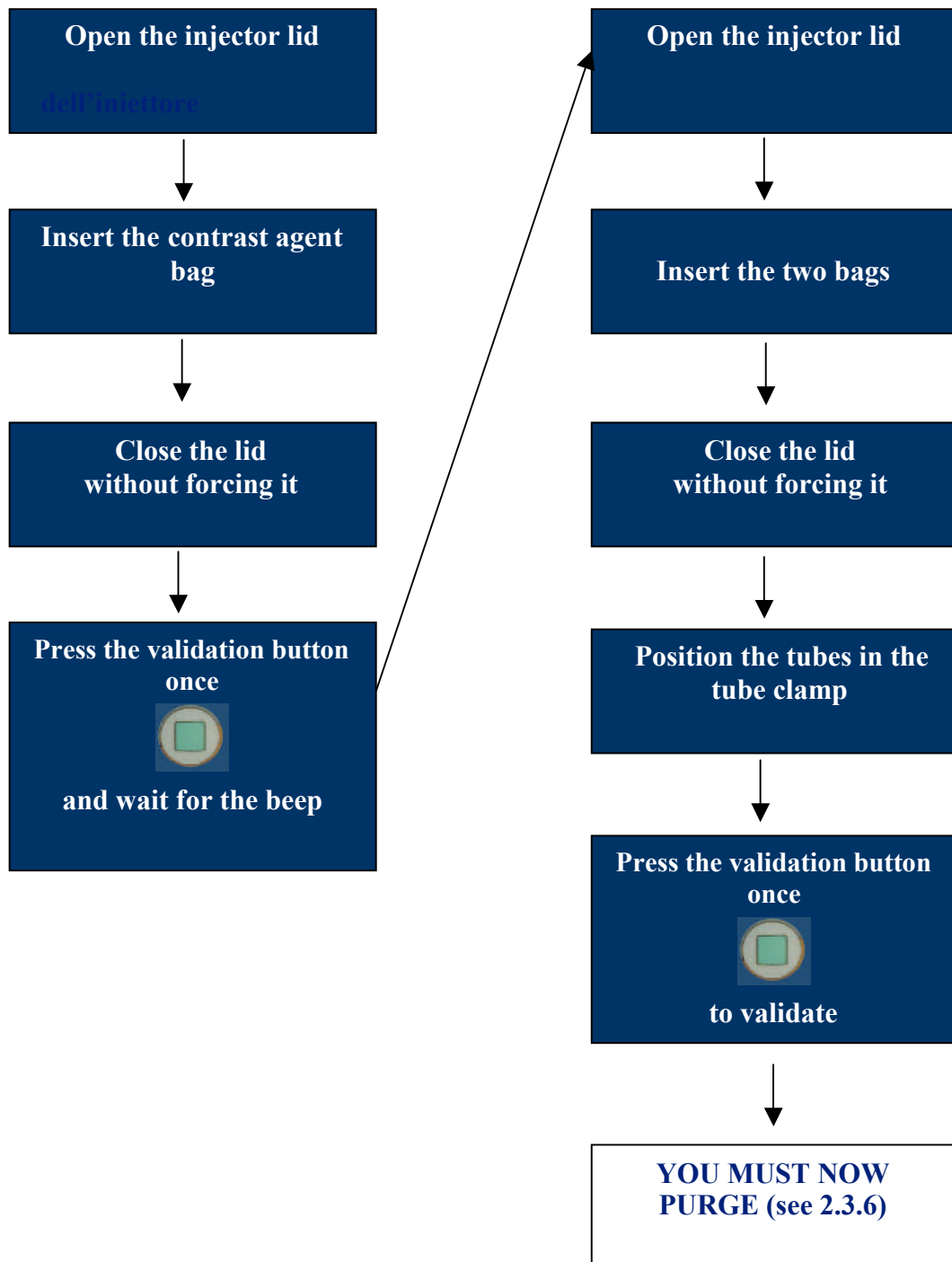
to apply pressure to the injector.
Message: 'Measuring saline,
please wait ...'

16 'Purge'



NOTE: To avoid an oversight, injector pressurisation is not possible until the tube clamp is activated, which shows that the tubes have been inserted into the tube clamps. In this case, the following message appears: 'Place the tubes into the tube clamps' and a sound signal is heard.

SUMMARY



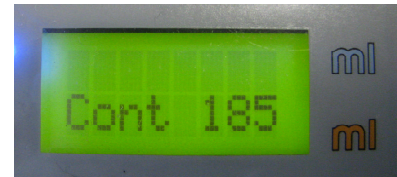
NOTE: The single-bag or double-bag cycle can be interrupted at any time by pressing any button, during movement of the actuator bag. The message 'CYCLE IS BEING CANCELLED' appears on the LCD screen.



2.3.6 Purging air

Purge in single-bag mode:

1 The orange light indicates the contrast agent to purge



2 Press the button



(rapid purge) and/or the button



(slow purge) until

contrast agent comes out of the tube.

Visually check that the whole line is filled with contrast agent.

3 Confirm that the purge is complete by pressing



(validation). The message 'Purge terminated' appears and the indicator light blink rapidly. They then remain lit.

Purge in double-bag mode

The blue light indicates the saline to purge. The blue light indicates the contrast agent to purge.



The button  (contrast) switches from one to the other as many times as necessary.

1 Press the tube.



(rapid purge) and/or



(slow purge) until saline or contrast agent comes out of

2 Press



(contrast)

3 Press the tube.



(rapid purge) and/or



(slow purge) until saline or contrast agent comes out of

Visually check that the both lines are filled with liquid.

4 Confirm that the purge is complete by pressing




(validation). The message 'Purge terminated' appears and the indicator light blink rapidly. They then remain lit.

For safety reasons, the purge phase cannot be validated without purging each of the bags at least once.

The purge is only effective when air has been totally removed from the tubes, meaning that there is no more air in the bag(s) .

Check that there is contrast agent or saline in the whole tube.

Purging is a manual operation to be performed only by qualified personnel trained in the use of this injector.

✚ After validating the purge, you can still go back and complete the purge if necessary
Press once on  (validation) and the message 'PURGE' blinks slowly.

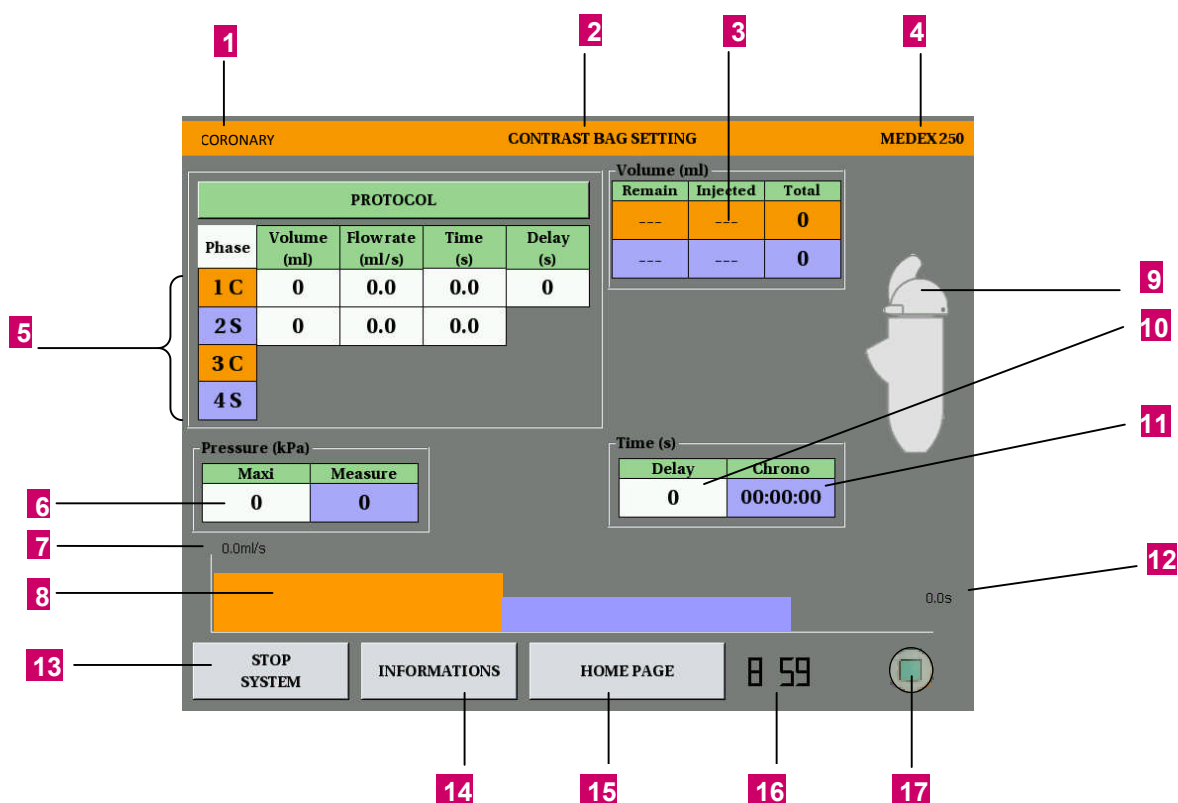
✚ The contrast agent (or saline) can be purged up to the Y in the line and the purge can be completed with saline (or contrast agent) until liquid comes out of the line.



2.4 Configuring the monitor

2.4.1 General description of the main injection screens

Main window:



1 Protocol name

2 System status

3 Information on volumes

4 Bag kit

5 Phase configuration

6 Configuration and information on pressure

7 Maximum flow rate

8 Graph

9 Injector head status

10 Injection synchronisation and delay

11 Time from injection start

12 Total injection time

13 Stop system

14 Open the information window

15 Return to the main menu

16 Time

17 Monitor validation button

Programming protocol phases (main window):

- 1 Select the number of phases by pressing on the corresponding number (1, 2, ...) in the left column (unused phases disappear).
- 2 Enter the volumes, flow rates and durations by pressing on the empty box in the 'PROTOCOL' table that you wish to change. Confirm each value with OK.

Volume (ml)

0

Name of parameter modified

Value entered

7 8 9 <---

4 5 6 Cancel

1 2 3

0 OK

Note: Enter the volume and the flow rate: the duration is calculated automatically
Enter the volume and the duration: the flow rate is calculated automatically

Note: The 'delay' table offers two possibilities:

- Pause between two phases and resumption with the injection button (manual delay)
- Time between two phases with automatic resumption after the time period (automatic delay)
- Pause between two phases: press the injection button to resume the injection
- Delay between the end of the preceding phase and the beginning of the following phase

Delay (s)

0

Time (seconds) between 2 phases

7 8 9 <---

4 5 6 Cancel

1 2 3 Pause

0 OK

Pause between 2 phases
→ press the injection button to start the injection

- 3 Press 'PHASE' to change the order of product injection (double-bag version): the 'PHASE' blinks blue and white. Select the phase by pressing on the corresponding number (1, 2, ...) in the left column (the phase changes colour: orange for a contrast agent injection and blue for a saline injection. Press 'PHASE' to validate.



Information on volumes:

- Remaining: volume of liquid remaining in the bag(s)
- Injected: volume of liquid injected
- Total: total volume to inject

Single-bag

Volume (ml)		
Remain	Injected	Total
185	6	10

1 2 3

Double-bag

Volume (ml)		
Remain	Injected	Total
35	100	100
115	25	80

4 5

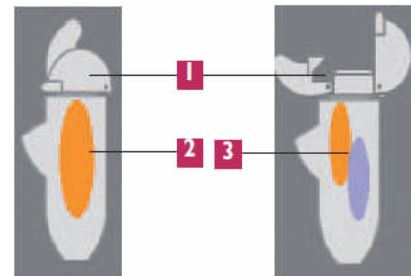
- 1 Volume remaining in bag
2 Volume injected into patient
3 Total volume to inject

- 4 Volume of contrast agent
5 Volume of saline

Bag levels:

Visualises the injector head and bags

- 1 Position of lid and spout
2 For a single-bag injection:
Contrast agent bag status
3 For a double-bag injection:
Positions of saline bag
and contrast agent bag



Programming the pressure:

Pressure can be programmed in two units: psi or kPa. The unit can be selected by opening the information window (see 2.6.2)

- 1 Max.: Enter the pressure limit during the injection using the number pad and confirm by pressing OK.
2 Measure: Measures the instantaneous injection pressure.

Pressure (kPa)	
Maxi	Measure
1000	104

1 2

Warning:

The time for detecting an occlusion depends on the maximum pressure chosen: the closer the measured pressure is to the maximum pressure entered, the shorter the time for detecting an occlusion.

Medex refuses all responsibility in the event of an incident.

Main menu:

From here you can go back to the home page to change the mode:
single-bag ↔ double-bag or to display the error log.

Protocol:

Opens the protocol window to display, select, write, save or delete a protocol (see 2.4.2).

Information:

Opens the information window (see 2.6) :

- to change a pressure unit
- to correct the date and time
- to display the injection history
- to select a bag kit
- to update the software

Stop system:

Stops the injection system at the end of the workday (see 2.7.2).

2.4.2 Saving and deleting a protocol

Saving a protocol:

- 1 Fill in the phase table and maximum pressure
- 2 Press **PROTOCOL** in the main window
- 3 Press **SAVE**, and a window for naming the protocol is displayed.
- 4 Enter the protocol name (14 characters, i.e. letters, figures, spaces)

The screenshot shows a 'Protocol' window with a text field containing 'PROTOCOL-3'. Below the text field is a grid of buttons for letters A-Z, digits 0-9, and special keys. At the bottom are three keyboard layout buttons: 'Azerty', 'Qwerty', and 'Qwertz'.

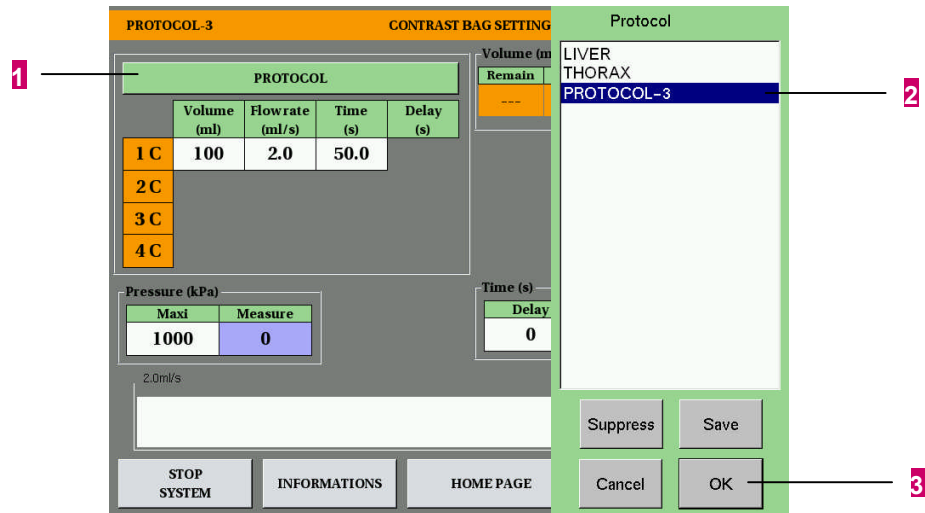
- 5 Confirm with **OK**

The entered name appears at the top left in the orange bar of the main window. If you open the protocol selection window, the new protocol is available along with the existing protocols.



Using existing protocols:

- 1 Press PROTOCOL
- 2 Select the PROTOCOL name

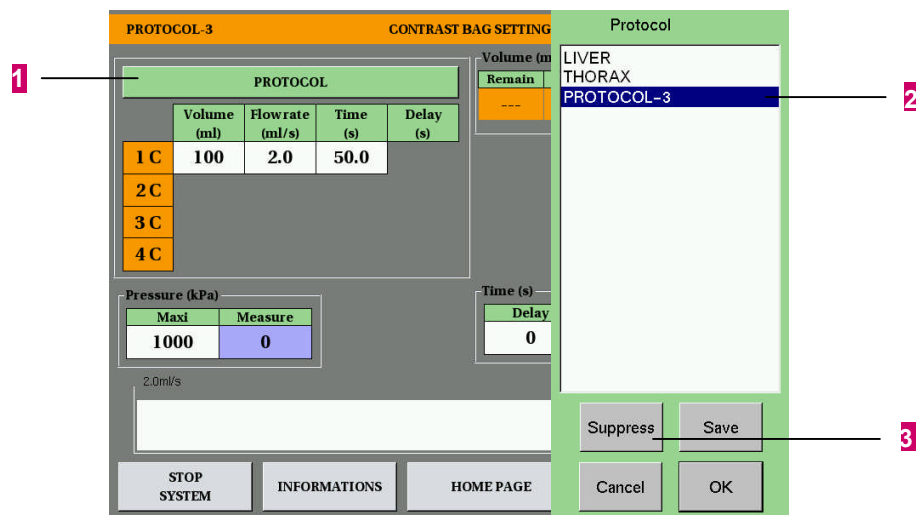


- 3 Press OK to confirm the protocol selection

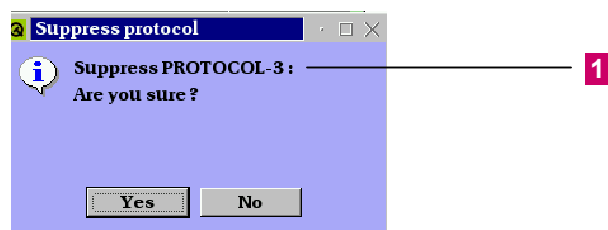
Note: You can switch from the AZERTY keyboard (or QUERTY or QUERTZ) to the QUERTY or QUERTZ keyboard (or AZERTY)

Deleting a protocol:

- 1 Press PROTOCOL
- 2 Select the PROTOCOL to delete



- 3 Press suppress



- 1 Name of protocol to delete

 Confirm with **Yes**



2.4.3 Synchronising X-rays and timers

Synchronising X-rays and timers:

Press Delay button to set two parameters.

Delay button

Time (s)	
Delay	Chrono
0	00:00:00

- Synchronise SBI → X-rays (ticked)
The injector controls the start of the X-ray device, depending on the programmed delay. A beep indicates the end of this delay.
- Synchronise X-rays → SBI (not ticked)
The X-ray device controls the injector start. Select the injection start mode in the information window 'Scanner' (see 2.6.1)

0	<input checked="" type="checkbox"/> SBI → RX		
7	8	9	<---
4	5	6	Cancel
1	2	3	
0	OK		

By default, the injector uses the manual synchronisation mode with the time at 0.

0	<input checked="" type="checkbox"/> SBI → RX		
7	8	9	<---
4	5	6	Cancel
1	2	3	
0	OK		

Synchronisation requires special connections between the injector and the X-ray device.

For more information, contact Medex or the representative in your country.

2.5 Injection

2.5.1 Preparing the injection

Configuring phases

The injection procedure can be programmed by selecting:

- the number of phases
- the volumes injected
- the injection flow rate
- the delay between phases

Note: With two bags, the injection solution can be selected for each phase.

Single-bag version

		<div><div>B</div><div>C</div><div>D</div></div>			
		Volume (ml)	Flowrate (ml/s)	Time (s)	Delay (s)
A	1 C	100	3.0	33.3	0.0
	2 C	40	2.0	20.0	
	3 C				
	4 C				

A Select the number of phases in the protocol → phases not selected disappear

B Select the volume → a number pad for entering the volume appears

- Enter the volume
- Confirm with OK → the volume is displayed in the selection window

C Select the flow rate → a number pad for entering the flow rate appears

- Enter the flow rate
- Confirm with OK → the flow rate is displayed in the selection window
- the phase duration is calculated automatically and is displayed

D Select the delay → a number pad for entering the delay appears

- Enter the delay
- Confirm with OK → the delay is displayed in the selection window

Note: step D is required if a delay is authorised between two phases.



Double-bag version

		C	D	E
A	B			
Phase	Volume (ml)	Flowrate (ml/s)	Time (s)	Delay (s)
1 C	110	3.0	36.7	0
2 S	20	2.0	10.0	6
3 C	50	3.0	16.7	0
4 S	20	2.0	10.0	

- A** • Select the type of phase by pressing Phase → the phase blinks blue and white.
- Select the solution in each phase by pressing the corresponding buttons → the button turns from orange to blue to indicate the type of solution injected.

Example:

Two contrast agent phases are followed by two Alternating contrast agent and saline phases

Phase	Volume (ml)
1 C	
2 C	
3 S	
4 S	

Phase	Volume (ml)
1 C	
2 S	
3 C	
4 S	

- To terminate the selection of the type of phase, again press the phase button → the phase button no longer blinks and the configuration window reappears
- B** • Select the number of phases in the protocol → Phases that are not selected disappear.
- C** • Select the volume → a number pad for entering the volume appears.
 - Enter the volume
 - Confirm with OK → the volume is displayed in the selection window
- D** • Select the flow rate → a number pad for entering the flow rate appears
 - Enter the flow rate
 - Confirm with OK → the flow rate is displayed in the selection window. The duration of the phase is calculated automatically and is displayed.
- E** • Select the delay → a number pad for entering the delay appears.
 - Enter the delay.
 - Confirm with OK → the delay is displayed in the selection window.

Note: step E is required if a delay is authorised between two phases.

Configuring maximum pressure

The maximum pressure is the pressure limit during the injection.

- ✚ Select the button maximum pressure → a number pad for entering the pressure appears
- ✚ Enter the pressure
- ✚ Confirm with **OK** → the pressure is displayed

Pressure (kPa)	
Maxi	Measure
1000	104

The boxes for maximum pressure and measured pressure blink red when the current pressure is approaching the maximum pressure. A sound alarm (5 beeps) is heard when the boxes begin blinking red. The monitor beeps at the end of the injection.

2.5.1 Starting the injection

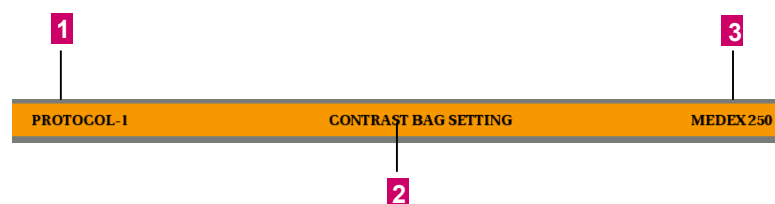
Before starting the injection, the following operations must be carried out:

- 1 Validate on the injector head (see 2.3.5): purge
- 2 Programme the following parameters:
 - number of phases,
 - volumes,
 - flow rates,
 - phase durations (Note: automatically calculated if the volumes and flow rates are configured)
- 3 Validate on the monitor by pressing the validation button



When the monitor is activated, all the recorded parameters are checked.

When the injector head is ready, the orange bar displays 'HEAD READY' to confirm that the monitor is programmed and gives the system status:



- 1 Name of protocol selected
- 2 System status
- 3 Name of bag kit



Start the injection:

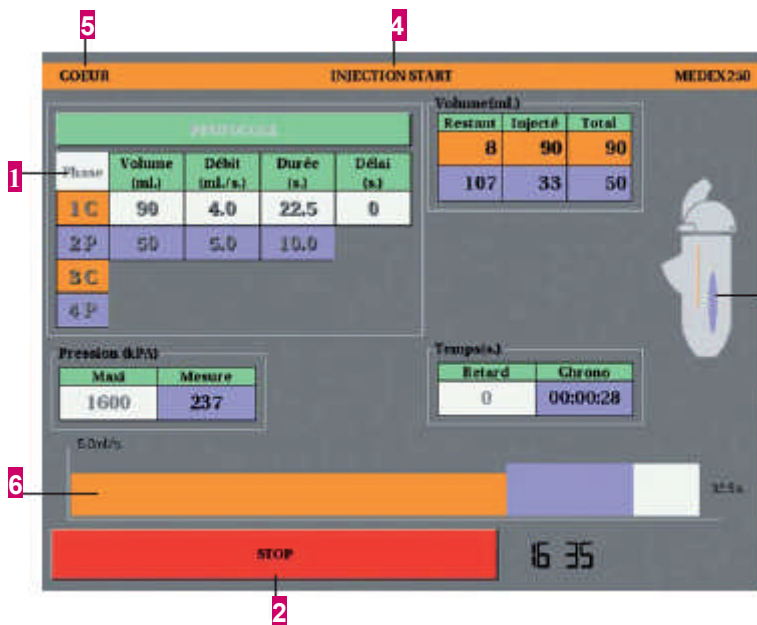
This can be done in two manners:

- Press once on the manual controller
- Press once on the **injection button** on the injector head



2.5.3 Monitoring the injection

Certain characters turn grey and inactive after the monitor is activated.



- 1 Phase
- 2 STOP button
- 3 Visualisation of bags
- 4 Injection status
- 5 Name of protocol selected
- 6 Graphic visualisation of the injection

Ongoing injection phase:

The ongoing injection phase also corresponds to a colour code: the phase is highlighted **in blue for saline** and **in yellow for contrast agent**.

Single-bag					Double-bag				
	Volume (ml)	Flowrate (ml/s)	Time (s)	Delay (s)	Phase	Volume (ml)	Flowrate (ml/s)	Time (s)	Delay (s)
1 C	10	1.0	10.0		1 C	100	3.0	33.3	0
2 C					2 S	80	5.0	16.0	
3 C					3 C				
4 C					4 S				

1 Ongoing injection phase

Information on volumes:

Single-bag			Double-bag		
Volume (ml)			Volume (ml)		
Remain	Injected	Total	Remain	Injected	Total
185	6	10	35	100	100
			115	25	80

Explanation and legend on page 28

Pressure measurement:

Pressure is measured in the injector head and is immediately displayed on the screen

Pressure (kPa)	
Maxi	Measure
1000	104

1 Maximum pressure entered
2 Pressure measured during the injection



2.5.4 Procedure for stopping the injection

Pause during injection:

An injection can be stopped temporarily. This can be done in two manners:

-  Press once on the manual controller
-  Press once on **INJECTION** on the injector head



The status bar blinks. 'Injection interrupted' appears on the orange bar at the top. The message 'pause' blinks on the injector head.

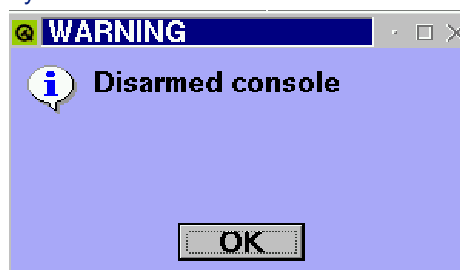
To resume the injection, again press once on the manual controller or on **INJECTION** on the injector head.

Permanent emergency stop during the injection:

If necessary, the injection can be permanently stopped by pressing **STOP**.



The following dialogue box is displayed:



The message 'EMERGENCY STOP' blinks for several seconds on the injector head.

-  Confirm the dialogue box with **OK**

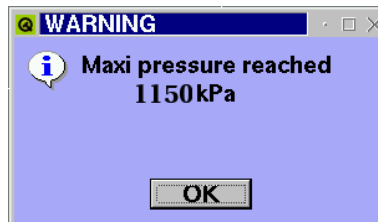
The injector head remains activated. Another injection can be started by re-activating the monitor.

2.5.5 Safety procedures during the injection

Maximum pressure reached:

If the pressure during the injection exceeds the maximum pressure programmed, the injector stops the injection.

The following dialogue box is displayed:



The message 'MAXIMUM PRESSURE' blinks for several seconds on the injector head.



Confirm the dialogue box with **OK**

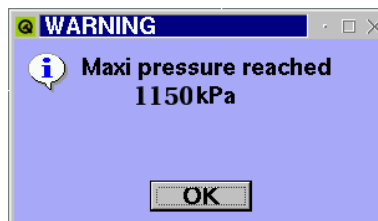
The injector head is inactivated. Check that there are no obstructions or folds.

Inactivating the head:

The injector head is inactivated by pressing any button on the injector head (except for the 'start injection' button).

The injection is stopped.

The following dialogue box is displayed:



Head inactivated

The message 'HEAD INACTIVATED' blinks for several seconds on the injector head.



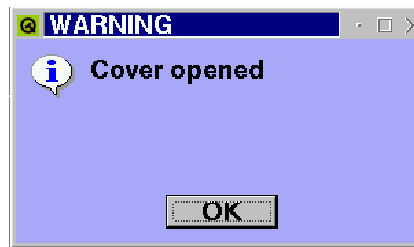
Confirm the dialogue box with **OK**

The injector head remains activated. Another injection can be started by re-activating the monitor.



Lid open during injection:

If the lid of the injector head is opened, the injection is stopped. The following dialogue box appears:



The message 'Please wait, lid open' appears on the injector head.

☒ Confirm the dialogue box with **OK**

The injector head is inactivated. The actuator bag opens.

2.5.6 Return to reinstalling the bag(s)

1 New bags can be installed during handling in two manners:

☒ press  on the monitor

☒ press  on the injector head

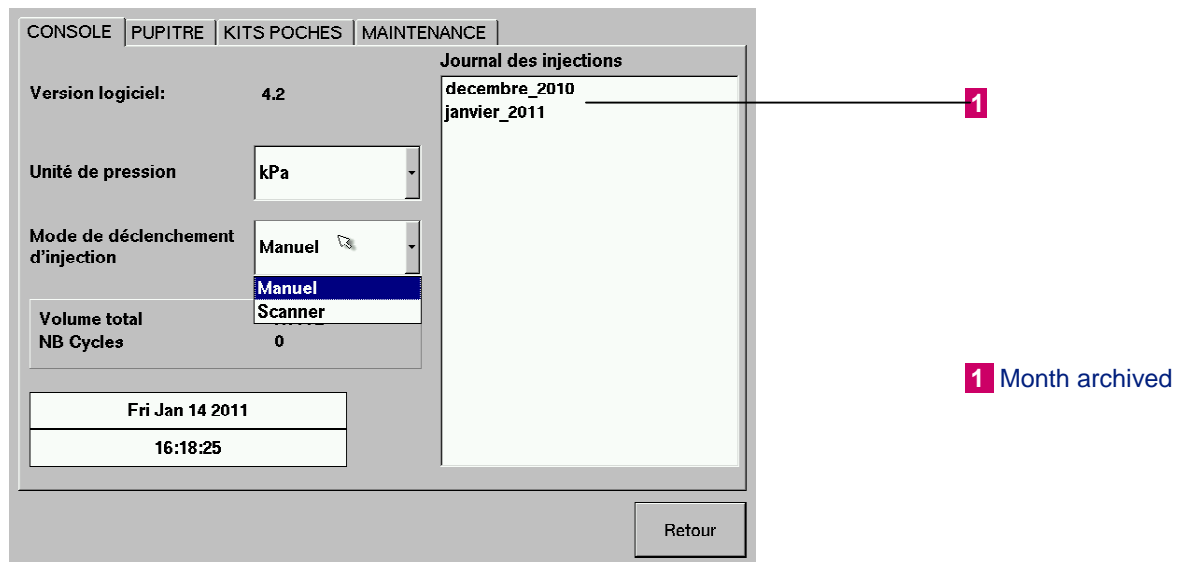
2 Confirm by again pressing



The message 'OPEN' blinks for several seconds on the injector head.

2.5.7 Injection history

The injections are recorded and classified by month.



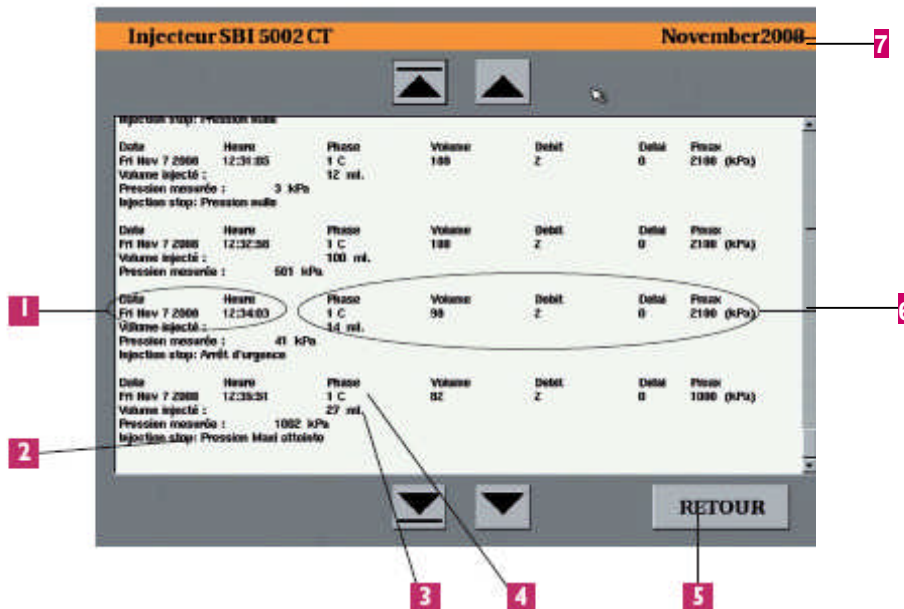
■ Select a month to consult the injection history

In the single-bag mode, only single-bag injections are displayed.

In the double-bag mode, only double-bag injections are displayed.



A new window opens displaying the injection history for the selected month:



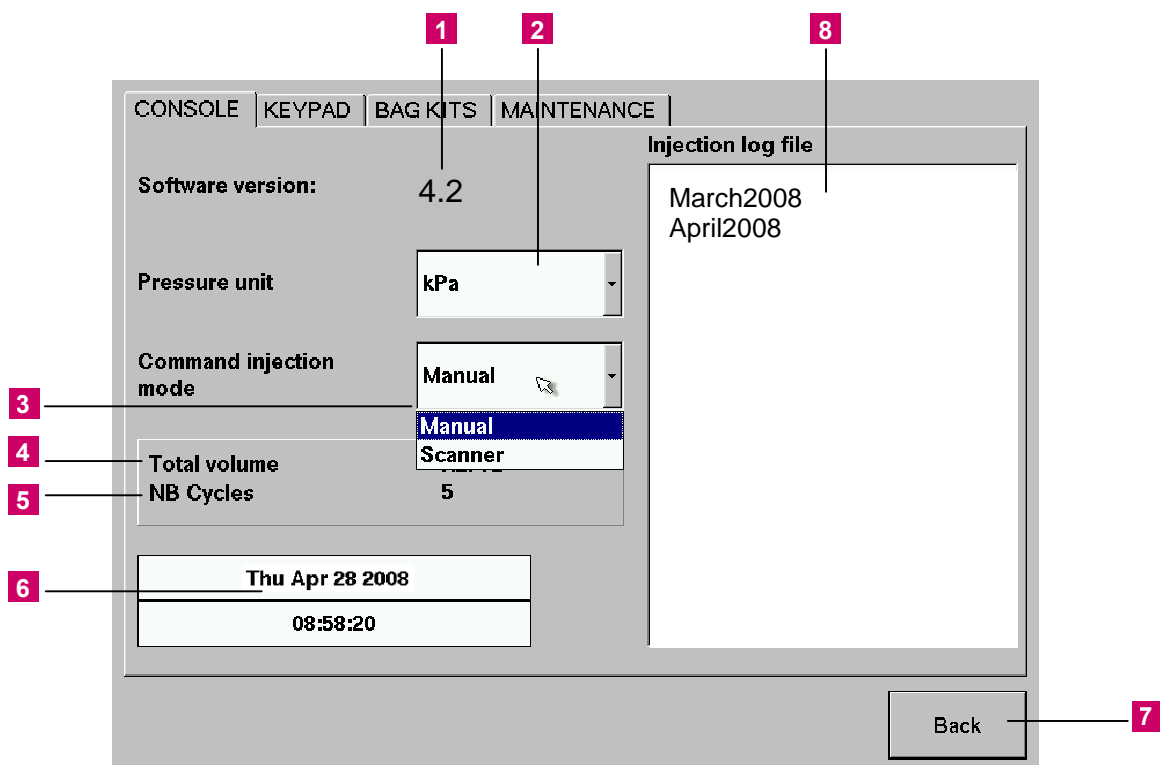
- | | |
|--------------------------------------------|-------------------------------------------|
| 1 Date and time of injection | 5 Return to the information window |
| 2 Maximum pressure measured | 6 Protocol recorded |
| 3 Volume of contrast agent injected | 7 Month and year |
| 4 Type of injection phase | |

Note: The injection history also indicates the following:

- emergency stop,
- maximum pressure reached.

2.6 Information window

2.6.1 Monitor tab



1 Software version (see 2.6.6 for updating)

2 Pressure unit selection (kPa/psi)

3 Injection start mode (Manual/Scanner). The scanner mode is displayed in the main window 'Scanner start mode inactive'.

4 Volume of solution injected by the injection system

5 Number of injections since the first use of the injection system

6 Button for changing the date and time

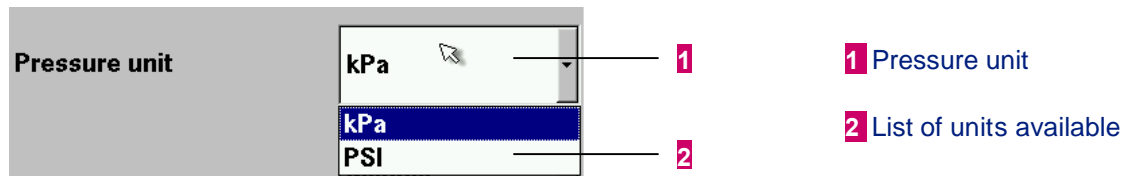
7 Return to the injection window

8 Select the injection history

The message 'Control panel inactive. Close the information menu' is displayed on the injector head.



Selecting the pressure unit:

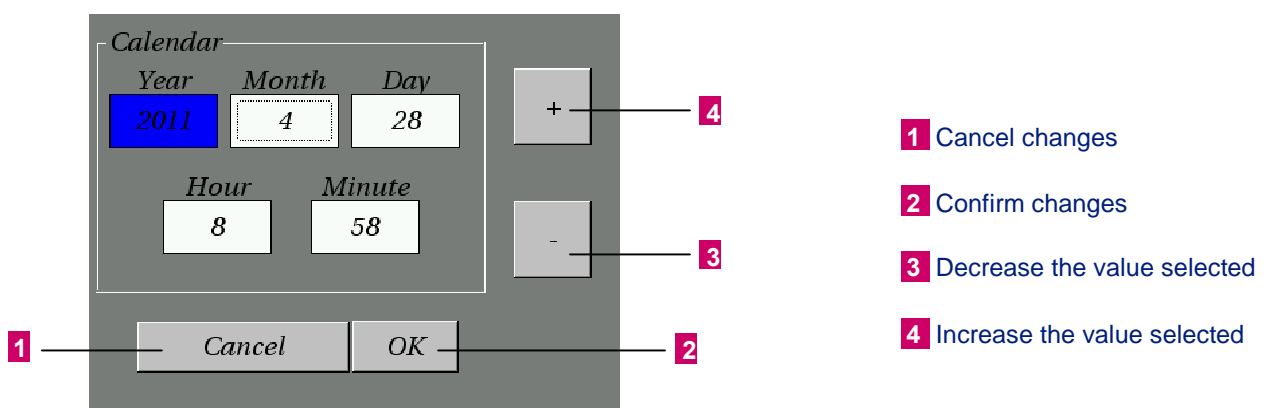
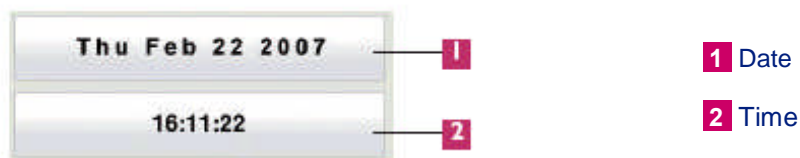


☒ Select psi or kPa by pressing the selection bar.

Changing the date or time :

The date and time can only be changed before inserting the bag(s) or after removal of the bag(s). The orange bar displays:

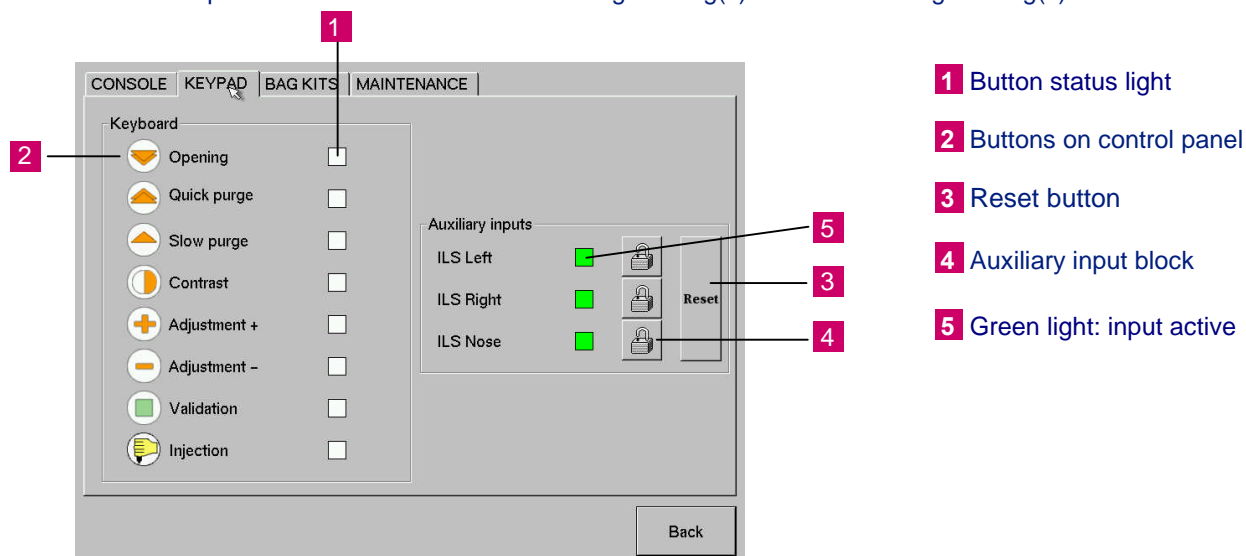
☒ Select the date or time in the **monitor** tab



- ☒ Select the data to change: the button turns blue
- ☒ Set using + or -
- ☒ Confirm the changes with **OK**

2.6.2 Control panel tab

The control panel tab is available before inserting the bag(s) or after removing the bag(s).



This tab is used to check whether the injector head is functioning and indicates the status of the control panel buttons. It also provides information of the status of auxiliary inputs.

The message 'control panel testing' appears on the injector head.

☒ Check the status of the buttons on the injector head by pressing the button on the injector head. On the monitor, the box corresponding to the button being pressed turns green if the button is active.

☒ Check the status of auxiliary inputs by closing the spout and/or lid. On the monitor, the box corresponding to the auxiliary input turns green if the auxiliary input is active.

Blocking/unblocking an auxiliary input:

If one of the auxiliary inputs is damaged, the injector will no longer function.

In an emergency, the damaged auxiliary input can be blocked to continue injections.

Blocking an auxiliary input may have serious consequences.

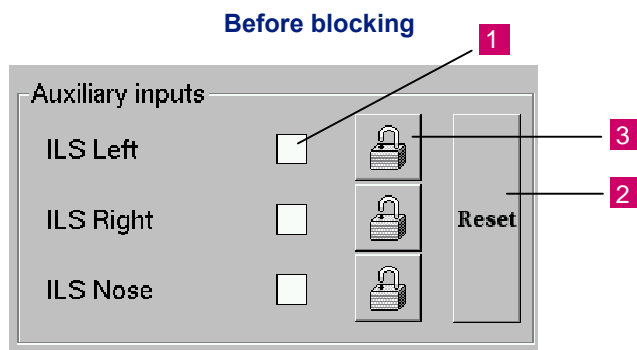
Medex refuses all responsibility in the event of an incident.

Contact Medex as rapidly as possible in the event of damage.

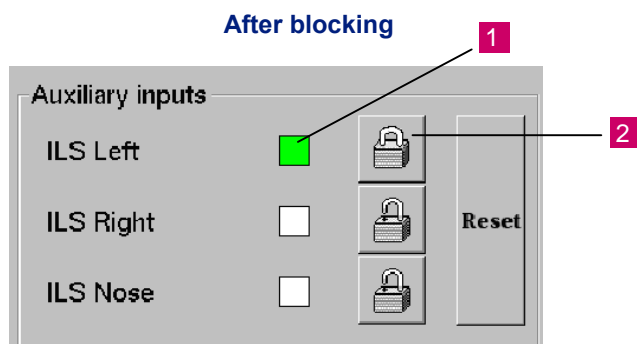


Blocking an auxiliary input:

- ✚ Select the damaged input button by pressing on the padlock
The padlock locks and the box turns green.



- 1** White light
- 2** Reset button
- 3** Padlock unlocked



- 1** Green light → input active
- 2** Padlock locked → input forced

Note: Only one input can be blocked at a time

Unblocking an auxiliary input:

- ✚ Press **Reset** to the right of the padlock

The padlock unlocks and the input light turns white

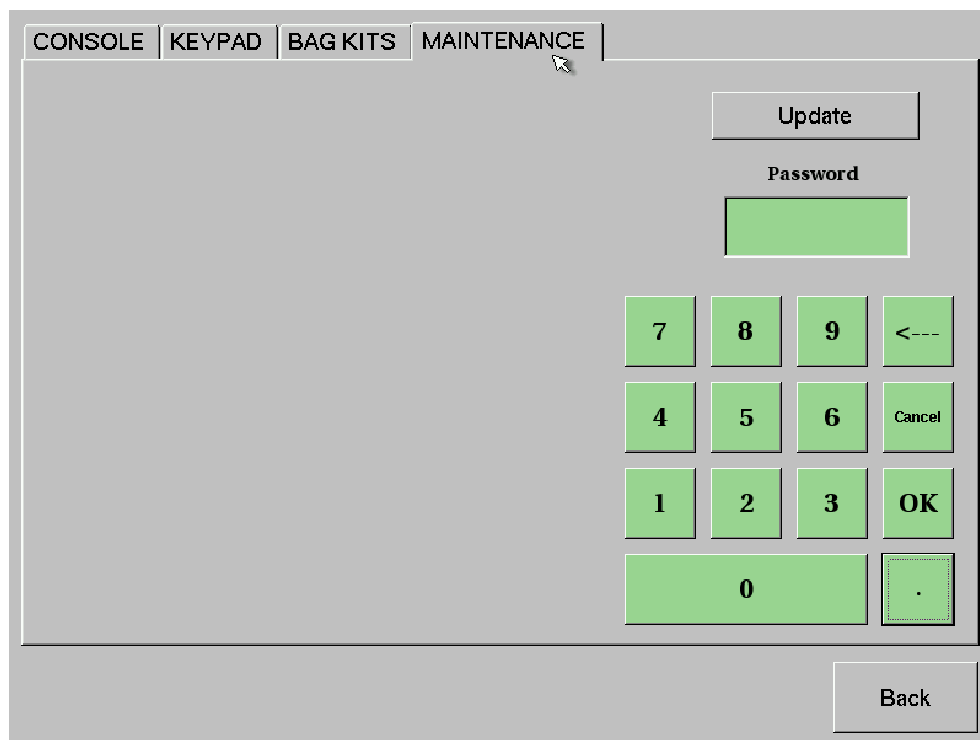
2.6.3 Bag kit tab

This tab is used to select the bag kit (see 2.3.3)

2.6.4 Maintenance tab

This tab is used for maintenance and software updating.
The software is updated using a USB key supplied by Medex.

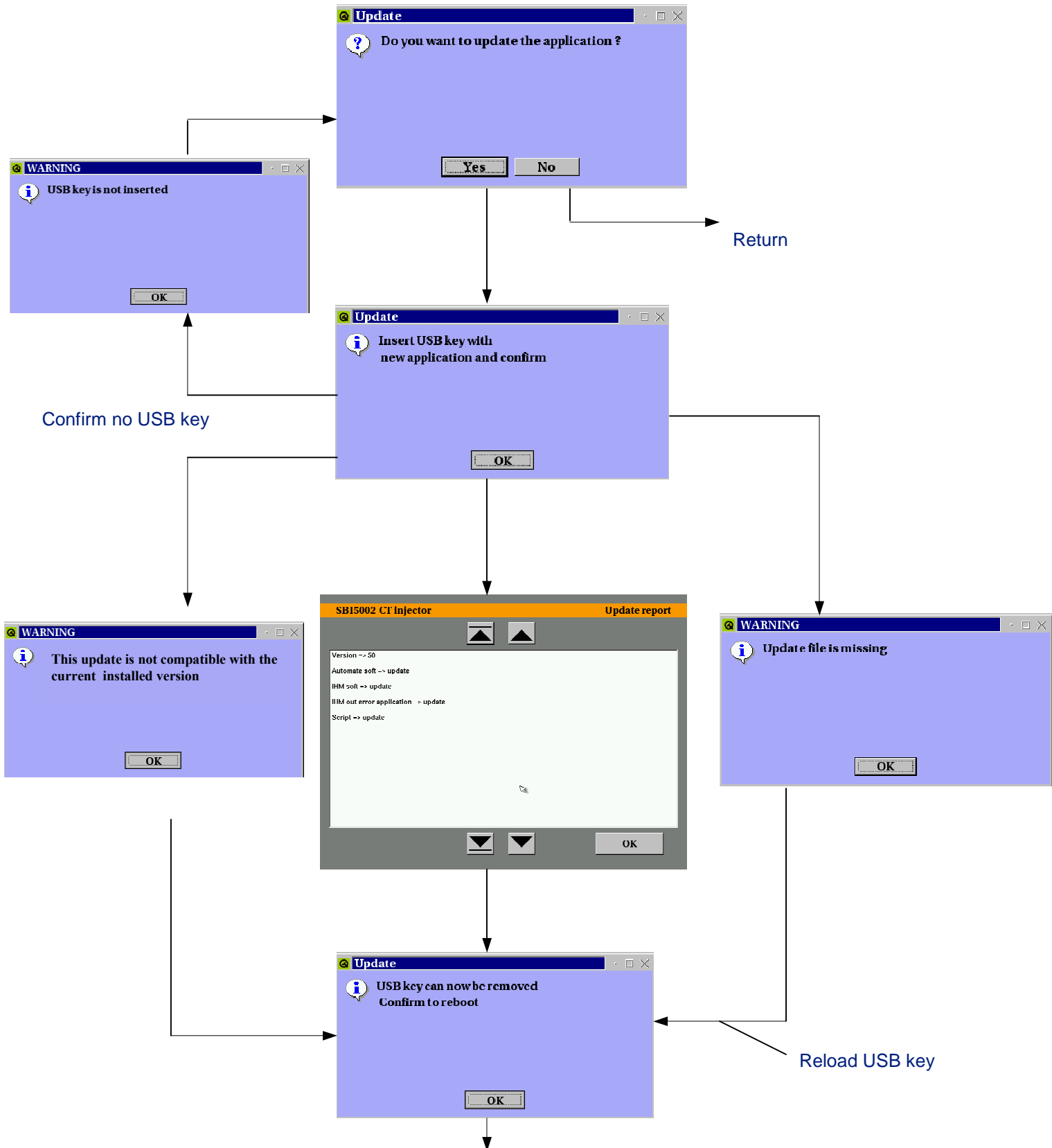
 Press 'Update'



The screenshot shows a software interface with four tabs at the top: CONSOLE, KEYPAD, BAG KITS, and MAINTENANCE. The MAINTENANCE tab is selected, indicated by a mouse cursor. The main area of the MAINTENANCE tab contains an 'Update' button at the top right. Below it is a 'Password' label followed by a green rectangular input field. To the right of the input field is a numeric keypad with buttons for digits 0-9, a left arrow, and a decimal point. Additionally, there are 'Cancel' and 'OK' buttons. At the bottom right of the MAINTENANCE tab area is a 'Back' button.

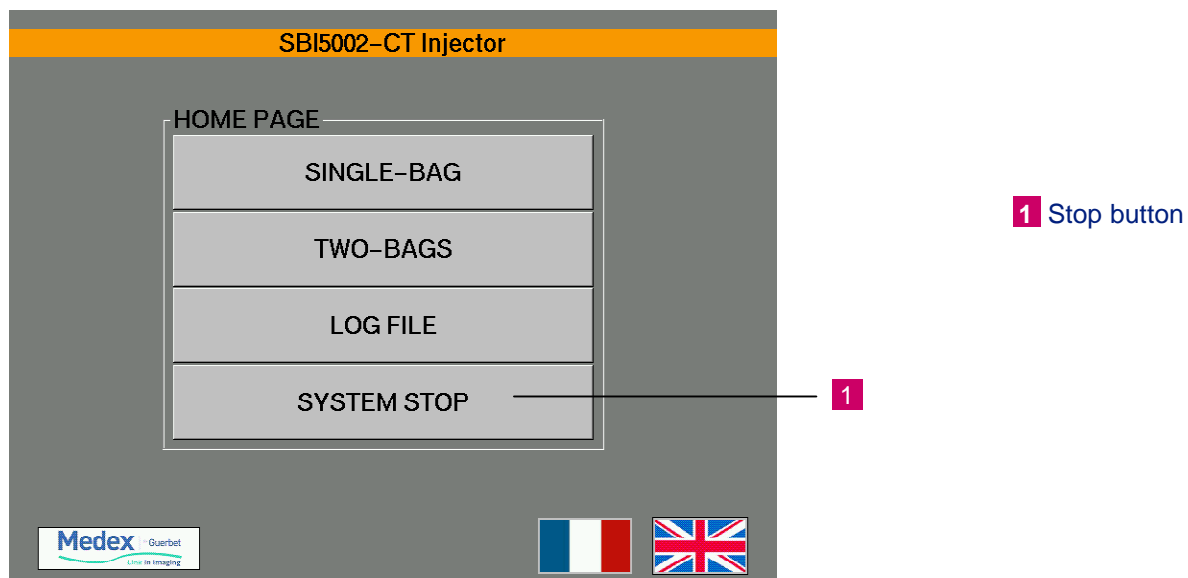
Note: Maintenance is only used by Medex technicians or certified personnel.

Update diagram



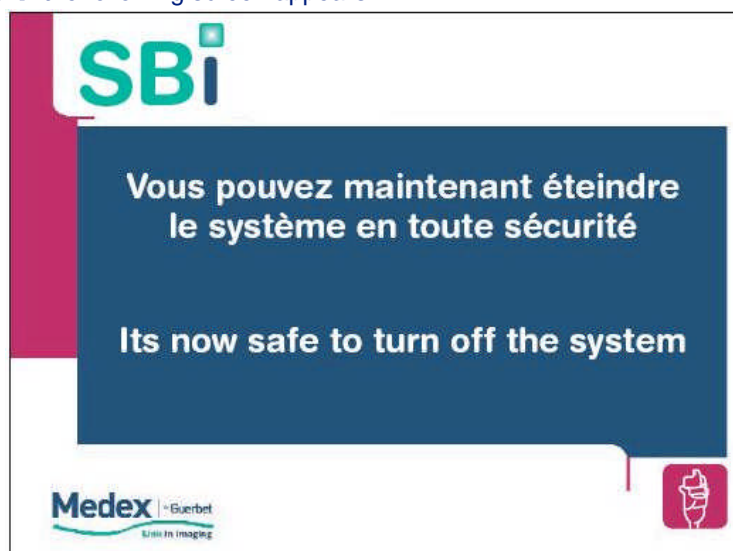
2.7 Stopping the injector

2.7.1 Stopping from the home page



Press **STOP SYSTEM** → The following dialogue box is displayed: 'Stop application?'

Confirm with **Yes** → the following screen appears:



Shut off power supply



2.7.2 Stopping from the main window after the start phase

✚ Remove the bag(s).

✚ Press 'Stop system'. After pressing **STOP SYSTEM**, the following dialogue box appears:



✚ Confirm with **Yes**. The following screens are displayed:



System stopping

the following screen appears :



✚ Shut off power supply

NOTE: Check that the lid and spout are closed on the injector head.

3. Safety reminders

3.1 Safety reminder: basic principles

Contrast agent injections require compliance with essential safety rules.

The most important problems are extravasation, air injection and nosocomial diseases.

To avoid them, it is advisable to comply with the following instructions:

- Every operator or radiologist who uses an injector **must undergo training** involving critical care practices and possible risks.
- Compliance with the following principle is absolutely essential: the **same person** prepares the injector (filling, purging), connects the patient and **starts** the injection according to a selected programme whose parameters have been confirmed.
- During the first seconds of the injection, it is strongly recommended that an operator **remain near the patient** to detect possible extravasation (visually or by palpation).
- The same person, complying with the obligatory rules of hygiene, replaces the consumables (soft bag and connectors) if it is a bag or patient line with a two-level check valve. It is advisable to install the new preparation systematically without waiting for the patient to be disconnected.

The injector is ready for the next patient: the bag has been filled and purged and the line is protected.

Do not:

- take over preparation from another operator,
- wait too long before preparing the injector for a new patient (changing bags or patient connection, purging, etc.).



3.2 Procedures for checking and detecting failures

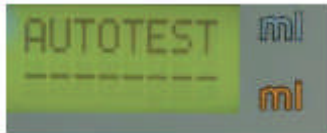
3.2.1 Checking sound alarms

If a beep is heard from the injector and then the monitor after turning on the power, the sound alarms are functioning.

3.2.2 Checking functional safety

Injector head:

When you start the machine, the control panel displays the following message:



This message shows that the integrated electronic system is being checked

The following message then appears:



It indicates the software version as well as the progress of synchronisation with the monitor. After 10 seconds, synchronisation is terminated and the display disappears before the user starts the programme.

It is also possible to check on the spout on the monitor, in the control panel tab (see 2.6.2) the functional status of the lid sensors.

Power unit:

The power unit is synchronised with the monitor when the injection system is started. The software interface constantly checks the status of the main components of the power unit, i.e. the position of the motor, which varies, and an I/O module that controls the hydraulic cylinders, and gives the status of various sensors.

In the event of a problem, [a dialogue box](#) automatically informs the operator of a defective connection and the component involved.

Monitor:

Monitor status can be checked by making sure that the menus are displayed on the screen after the power is turned on and that the buttons on the control panel are functioning properly.

3.2.3 Repair guide, failure detection

In the event of malfunction, shut the device off immediately and disconnect it rapidly from the patient. Check that everything is functioning properly again before reconnecting. Turn the system power on, activate it and proceed with a test injection. If the problem is resolved, reconnect the patient. If the failure message is still displayed and cannot be corrected, or if the injector still does not function properly, **STOP USING** the SBI injection system until the problem has been correctly diagnosed and resolved. Contact your local Guerbet distributor or a Medex certified distributor (contact information on the last page).

3.3 Cleaning the injector

Monitor:

The touchscreen must be cleaned regularly, preferably with a special cloth for screens. If not, use absorbent paper with surgical alcohol. **DO NOT SPRAY A CLEANING PRODUCT DIRECTLY ONTO THE SCREEN**, it could penetrate the control box and damage the monitor.

During normal use, special decontamination is unnecessary.

Injector head:

If contrast agent has been spilled onto the injector head, clean it with a sponge soaked in hot soapy water.

Do not use an abrasive product or a scouring pad.

To disinfect, use wipes soaked with a disinfectant.

Power unit:

During normal use, special cleaning is unnecessary.

However, it can be cleaned with a rag soaked with surgical alcohol. **DO NOT SPRAY A CLEANING PRODUCT DIRECTLY ONTO THE POWER UNIT**, it could penetrate the box and damage the injector.

To disinfect, use cleaning cloths soaked with a disinfectant.



3.4 Preventive maintenance of the injector

WARNINGS:

To maintain the performance and safety of the SBI injector, Medex by Guerbet recommends annual servicing.

This servicing is generally under the user's responsibility and may be obligatory, depending on local regulations.

The servicing operation must be performed by Medex certified personnel and/or the local distributor.

Modification or repair of the injection system by someone other than a Medex certified representative, and/or the local distributor, will result in a cancellation of the guarantee.

3.5 Symbols



Ground



Class 1



Refer to the manual

IP20 protection against the penetration of tools ≥ 2.5 mm in diameter.

CE 0459

Quality system in compliance with European Directive 93/42/EEC related to medical devices.

3.6 Transport

- The injector must be transported in its original packaging.
- Maximum relative humidity: 80%
- Temperature: 5 to 40°C

3.7 Recycling

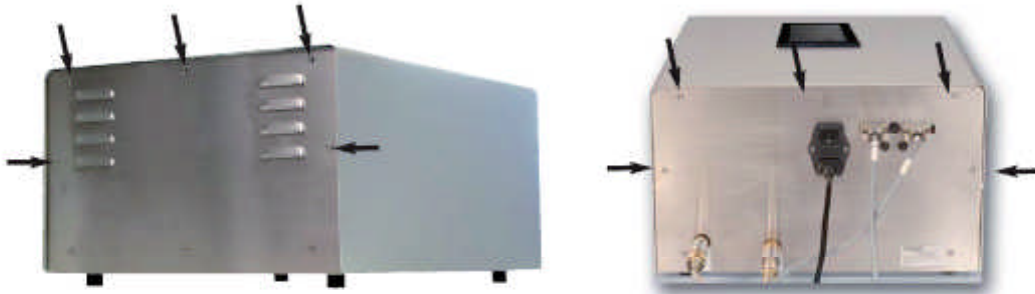
At the end of its lifespan, the injector must be returned to Medex or delivered to a recycling company.

3.8 Placing the cap before and after transport

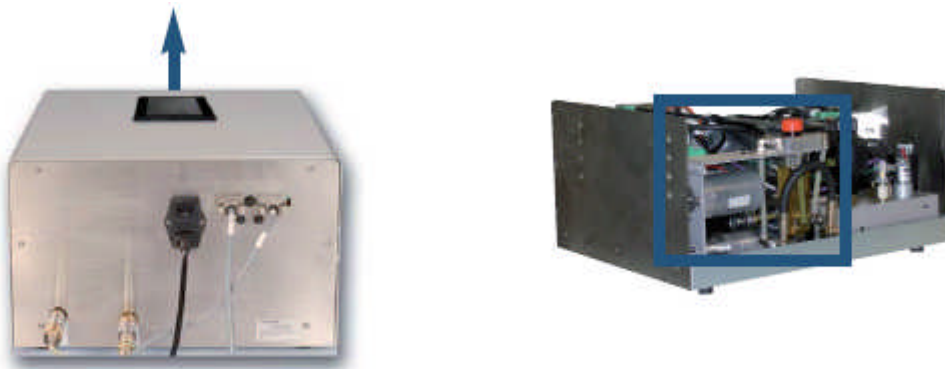
Before and after transport, the orange cap must be removed and replaced using 2.5 and 6 mm Allen keys.

After transport:

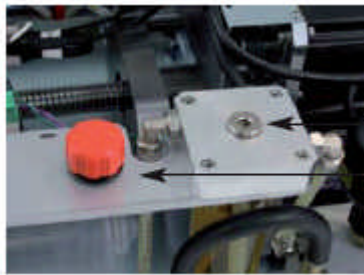
- 1** • Unscrew the ten screws on the power unit (five on each side) with the 2.5 mm Allen key



- 2** • Remove the cover. Warning: the fan on the cover is connected to the power unit. Take care not to damage this connection.



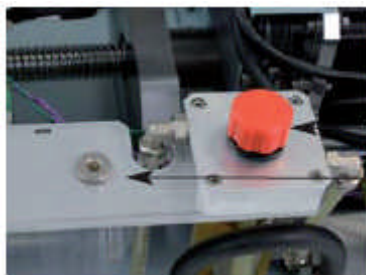
-
- 3** • Manually unscrew the orange cap on the reservoir and the metal cap with the 6 mm Allen key.



with the 6 mm Allen key

manually

- 4** • Reverse and screw the orange cap manually on the reservoir and the metal cap with the 6 mm Allen key.



manually

with the 6 mm Allen key

- 5** • Replace the cover and screw it on.



Before transport:

Carry out the same operation in reverse.



Glossary

ACTIVATION

Step preceding the injection consisting in checking the purge operation. Check that the injection parameters have been programmed and are consistent (activate the monitor). The injector has to be activated before starting an injection.

ACTUATOR BAG

Rubber bag within the injector head. The actuator bag surrounds the product bags (contrast agent, saline).

BAG KIT

Single-use set used for each injection. The kit used must be entered on the monitor. The injector (actuator bag) measures the volume depending on the kit selected.

CALIBRATION

In the calibration step, the injector calculates its reference position. The bags must be removed from the head and the lid must be closed. This obligatory step occurs automatically each time the device is turned on.

CONTRAST AGENT

Iodinated solution for injection used to enhance contrast in organs examined for diagnostic purposes.

CONTROL PANEL

Panel with an LCD screen located on the injector head. The control panel informs the user on the injector status. It controls all the functions involved in preparing the injection: bag insertion, pressurisation, purging and activation.

FILL FAST FILLER

Injector accessory provided as standard equipment with each injector. The filler is used to transfer bottle contents to Medex soft bags.

HYDRAULIC CONNECTOR

Sealed connection between the injector head and the power unit. The system can rapidly isolate the various components of the injector. The injector must never be turned on if any of the components are not connected.

LID

Top part of the injector that closes the injector head and maintains pressure. It is opened by pushing the green lock buttons laterally and tilting the whole lid backwards. It should be closed without force and must remain closed during injector pressurisation.

LOG

Record of events that occur during injector use. There are two logs: the injection log, which gives details about injections performed each month, and the injector error log.

LUER LOCK

Sealed connector.

MANUAL CONTROLLER

External manual controller connected to the monitor used for remote activation of the injection.

MONITOR

One of the three components of an SBI. It is generally placed next to the CT scanner control screen. The monitor has a colour touchscreen and a manual controller. It is used to program and monitor the injection.

POWER UNIT

Power box with hydraulic pressure generator. It controls bag squeezing in compliance with the protocol instructions and opens and closes the tube clamps on a double-bag injector (SBI 5002-CT).

PROTOCOL

Sequence of phases that can be saved for subsequent use.

SALINE

Normal saline used in conjunction with the contrast agent (double-bag mode).

SINGLE-BAG/DOUBLE-BAG

Injector usage mode. The mode must be selected in the general menu on the monitor. The single-bag mode is used for examinations that only require contrast agent. The double-bag mode is used for examinations that require contrast agent and saline.

SPOUT

Green pastic part located on the injector head, which tilts forward. Its position is detected with a sensor. It is used to guide and fix the tubes when the bags are inserted in the actuator bag.

TUBE CLAMP

Component situated on the right of the SBI 5002-CT injector head. It is used to select the liquid injected (pulsed bolus use). The tube clamp grips the tubes from each bag and must be activated manually during bag insertion, removal or during purges.

